

(2)

## PATENT ABSTRACTS OF JAPAN

(11)Publication number : 07-016218

(43)Date of publication of application : 20.01.1995

(51)Int.Cl. A61B 5/14

(21)Application number : 06-137684

(71)Applicant : BOEHRINGER MANNHEIM GMBH

(22)Date of filing : 20.06.1994

(72)Inventor : LANGE HANS  
ARGAUER HERBERT

(30)Priority

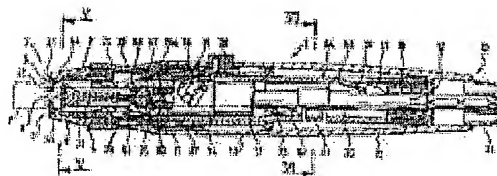
Priority number : 93 4320463 Priority date : 21.06.1993 Priority country : DE

(54) BLOOD LANCET DEVICE FOR COLLECTING DIAGNOSIS-PURPOSE BLOOD

(57)Abstract:

PURPOSE: To provide a blood lancet device capable of preventing all portion that possibly touches blood of a patient from being reused with reliability.

CONSTITUTION: A blood lancet device for collecting diagnosis-purpose blood comprises a housing 10, a lancet holder 11 held in the housing 10 movable for supporting a lancet 4, and a lancet drive mechanism 12 for driving the lancet holder 11 for the centesis or retreat motion. The blood lancet device holds in its dispensable member 3 a skin-touching part 5 and a lancet body 31 connected to each other with a predetermined breakage part interposed between their connection so as to separate them from each other upon the insertion of the dispensable member 3 into the blood lancet device.



## \* NOTICES \*

JPO and INPIT are not responsible for any damages caused by the use of this translation.

1.This document has been translated by computer. So the translation may not reflect the original precisely.

2.\*\*\* shows the word which can not be translated.

3.In the drawings, any words are not translated.

## CLAIMS

[Claim(s)]

[Claim 1]A blood lancet device (1) for blood extraction of diagnostic purposes characterized by

comprising the following.

Housing (10).

A lancet holder (11) movable within [ for supporting lancet (4) which consists of a lancet needle (33) fixed in a lancet main part (31) built with plastic material, and this lancet main part (31) ] housing (10).

Lancet drive mechanism (12) for making a puncture of a lancet holder (11) and movement toward retreat which are supporting lancet (4) drive is included in inside, This housing (10) has an exchangeable skin contact portion (5) which has an outlet opening part (6) for lancet (4) in the front end (2) which goes in the direction of a puncture, When this skin contact portion (5) uses a blood lancet device (1), it has a contact surface (42) for pushing against the skin, and this skin contact portion (5) and lancet (4), Component parts of a disposable member (3) which one use is meant and can be inserted by the front end (2) of housing (10) by handling operation of a single time are formed, This disposable member (3) is designed lancet (4) accept it with a skin contact portion (5), inserted, and get, Within this disposable member (3), lancet main part (31) of each other is connected with a skin contact portion (5), The 1st predetermined breaking part (52) that a skin contact portion (5) and a lancet main part (31) may separate mutually after a disposable member (3) is inserted in an end point between a skin contact portion (5) and a lancet main part (31).

[Claim 2] Lancet (4) has the chip protective cap (7) built with plastic material connected with a lancet main part (31) via the 2nd predetermined breaking part (53), The blood lancet device according to claim 1 in which dissociates after a disposable member (3) is inserted, and both predetermined breaking parts deal.

[Claim 3] The blood lancet device according to claim 2 with which it uses and throws away and a member (3) is designed so that the 1st predetermined breaking part (52) and the 2nd predetermined breaking part (53) may be separated by handling operation of a single time.

[Claim 4] The blood lancet device according to claim 1 with which a chip protective cap (7) is connected with a skin contact portion (5) at the end of an outlet opening part (6), and this connecting part is equipped with the 1st predetermined breaking part (52).

[Claim 5] The blood lancet device according to claim 2, 3, or 4 with which a skin contact portion (5) has been arranged toward the direction of a puncture of a lancet main part (31) at the front, and a chip protective cap (7) is extended through an outlet opening part (6) of a skin contact portion (5).

[Claim 6] The blood lancet device according to claim 1, 2, 3, 4, or 5 currently designed as an annular solid (41) in which a skin contact portion (5) forms only a front end surface of housing (10) substantially.

[Claim 7] If a disposable member (3) is inserted, lancet (4) in a lancet holder (11) will be inserted in impossible [ rotation ], The front end (2) of housing (10) is equipped with a rotation restriction stopper (58) for a skin contact portion (5), The blood lancet device according to claim 3, 4, 5, or 6 which may be separated when both predetermined breaking parts rotate a chip protective cap (7) to lancet (4) and a skin contact portion (5).

[Claim 8] A means (64) for ensuring for load of tension of a repetition of lancet drive mechanism (12) to be possible [ after removing lancet (4) located in a puncture which precedes, and a lancet holder between movement toward retreat (11) ], The blood lancet device according to claim 1, 2, 3, 4, 5, 6, or 7 which lancet drive mechanism (12) has.

---

[Translation done.]

\* NOTICES \*

JPO and INPIT are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.\*\*\* shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

---

## DETAILED DESCRIPTION

---

### [Detailed Description of the Invention]

[0001]

[Industrial Application]A lancet holder movable within [ for this invention to support the lancet which consists of a lancet needle fixed in housing, the lancet main part built with plastic material, and this lancet main part ] housing, About the blood lancet device for blood extraction of the diagnostic purposes which contain in inside the lancet drive mechanism for making the puncture of a lancet holder and the movement toward retreat (retraction) which are supporting lancet drive, This housing has an exchangeable skin contact portion which has an outlet opening part for lancet in the front end which goes in the direction of a puncture, and when this skin contact portion uses a blood lancet device, it has a contact surface for pushing against the skin. Said skin contact portion and lancet form the component parts of a disposable member which one use is meant and can be inserted by the front end of housing by handling operation of a single time, and this disposable member is designed lancet accept it with a skin contact portion, inserted into housing, and get.

[0002]

[Description of the Prior Art]In various illnesses, in order to deal in the numerical value (blood values) in specific blood, to inspect the Homo sapiens blood is needed. For this purpose, if only a little blood is extracted from the inside of the body in the form of the glob of blood by building a small punctured wound, it comes out enough and there are many a certain things. Especially an important example is diabetes mellitus and must inspect blood at an interval fixed about a glucose content.

[0003]A punctured wound suits a puncture device and mutual, and is usually built using the blood lancet device containing exchangeable lancet. The lancet holder which can insert one lancet exchangeable at once into it is contained in a puncture device. During puncture operation, a lancet holder is promptly moved in the direction of a puncture until it builds a small punctured wound into the portion of the body in which the chip of lancet comes out of the outlet opening part of a skin contact portion, and a skin contact portion is forced with lancet. With lancet, the after lancet holder retreats in the direction opposite to the direction of a puncture. The example of this type of lancet device is written in the US,4442836,B Description.

[0004]In this Description, the end of a puncture device with an outlet opening part is called the front end (anterior end), and the end of the opposite hand is called the back end (posterior end).

[0005]In order to avoid infection, new lancet must be used to each puncture operation. so, following each puncture operation, the lancet device written in the aforementioned United States Patent specification is discharged automatically [ used lancet ] from this device, when load of the tension is again carried out to this lancet device (ejected) -- it needs -- it is designed.

[0006]However, the danger of infection is produced also from the contact surface of the puncture device front end forced on the skin from the lancet itself. At the inside of the hospital sector using the same blood sampling equipment, or a clinic, especially this is applied to a different patient. When such, since the pathogen contained in a patient's blood may transfer, there is high danger of the infection to an acquired immunodeficiency syndrome, a hepatitis B virus, etc., for example.

[0007]In order to eliminate the danger of infection through a skin contact surface, the special skin contact portion exchanged with lancet in a known lancet device which was described above is devised. In this arrangement, lancet and skin contact portions are two independent parts assembled so that the unit which can use at the lower part end of a puncture device, and means one use may be formed. Such a unit that consists of the lancet and the skin contact portion

which mean one use is called a disposable member in this Description.

[0008]In a known lancet device, a skin contact portion is designed as a longwise sleeve which the length is about 1/3 of the length of the whole blood lancet device when it is in "an usable state" (i.e., when the preparation for use is complete), and encloses the lower part end thoroughly. Lancet is ahead supported by the elastic plastic strip and is located in a sleeve as independent component parts. Said elastic plastic strip drives the movement toward retreat following a puncture. When this device puts back manually the lancet holder covered with the sleeve type skin contact portion in the usable state, load of the tension is carried out. So, this device can carry out load of the tension again only within the case where a skin contact portion is first removed following a puncture. or [ that load of the device is carried out in tension as for this ] -- or, although it ensures that the disposable member which comprises a skin contact portion and lancet must be removed before a reuse is carried out, It does not prevent inserting the same disposable member again into housing, and carrying out a reuse following the tension re-load of removal of a disposable member, and a blood lancet device, with reliability. So, it cannot escape carrying out the reuse of the disposable member to intentionally accidentally (since the danger of following on it is disregarded).

[0009]

[Problem(s) to be Solved by the Invention]This invention is made in order to solve this problem, and it aims at preventing the reuse of a patient's blood and all the parts of the blood lancet device which may contact with reliability.

[0010]

[Means for Solving the Problem]In a lancet device of this invention, a skin contact portion and lancet main part of each other are firmly connected with this purpose in a disposable member, After a disposable member was inserted by the 1st predetermined breaking part by a joint of a skin contact portion and a lancet main part, it was finished by being devised as a skin contact portion and a lancet main part dissociating mutually.

[0011]Namely, in order that the aforementioned purpose may support the lancet 4 which consists of the lancet needle 33 fixed in the housing 10, the lancet main part 31 built with plastic material, and this lancet main part 31, It is the blood lancet device 1 for blood extraction of diagnostic purposes which contain the lancet drive mechanism 12 for making a puncture of the movable lancet holder 11 and the lancet holder 11 which is supporting the lancet 4 to inside, and movement toward retreat drive within the housing 10, This housing 10 has the exchangeable skin contact portion 5 which has the outlet opening part 6 for the lancet 4 in the front end 2 which goes in the direction of a puncture, When this skin contact portion 5 uses the blood lancet device 1, it has the contact surface 42 for pushing against the skin, and this skin contact portion 5 and the lancet 4, Component parts of the disposable member 3 which one use is meant and can be inserted by the front end 2 of the housing 10 by handling operation of a single time are formed, This disposable member 3 is designed so that the lancet 4 can accept and insert with the skin contact portion 5, and within this disposable member 3, the skin contact portion 5 and the lancet main part 31 of each other are connected, After the disposable member 3 is inserted in an end point between the skin contact portion 5 and the lancet main part 31, a blood lancet device, wherein it has the 1st predetermined breaking part 52 that the skin contact portion 5 and the lancet main part 31 may separate mutually can attain.

[0012]The lancet 4 has the chip protective cap 7 built with plastic material connected with the lancet main part 31 via the 2nd predetermined breaking part 53, It is preferred that dissociate after the disposable member 3 is inserted, and both predetermined fracture parts get, and it is preferred that use and throw away and the member 3 is designed so that the 1st predetermined breaking part 52 and the 2nd predetermined breaking part 53 may be separated by handling operation of a single time.

[0013]It is desirable, when the chip protective cap 7 is connected with the skin contact portion 5 at the end of the outlet opening part 6 and this connecting part is equipped with the 1st predetermined breaking part 52.

[0014]The skin contact portion 5 is preferred, when it has been arranged toward the direction of a puncture of the lancet main part 31 at the front and the chip protective cap 7 is extended

through the outlet opening part 6 of the skin contact portion 5, and when it is designed as the annular solid 41 which forms only a front end surface of the housing 10 substantially, it is preferred.

[0015] If the disposable member 3 is furthermore inserted, the lancet 4 in the lancet holder 11 will be inserted in impossible [ rotation ], It is preferred that it may dissociate when the front end 2 of the housing 10 is equipped with the rotation restriction stopper 58 for the skin contact portion 5 and both predetermined breaking parts (52, 53) rotate the chip protective cap 7 to the lancet 4 and the skin contact portion 5.

[0016] The means 64 for ensuring for load of tension of a repetition of the lancet drive mechanism 12 to be possible [ after removing the lancet 4 located in a puncture which precedes, and the lancet holder 11 between movement toward retreat ], It is preferred that the lancet drive mechanism 12 has.

[0017]

[Example] The feature of the blood lancet device of this invention is that it is in an insertion condition while the disposable member is inserted in the puncture device, and the skin contact portion is firmly connected with the lancet main part in this state (on indirect target [ Directly or ]). This insertion condition is maintained until a skin contact portion, lancets, or those both reach a tip position (using position) within a blood lancet device. In an insertion condition, since the lancet main part has connected with the skin contact portion firmly, it is not usable in a blood lancet device.

[0018] A lancet main part, therefore lancet are released so that the puncture for changing a disposable member into an usable state from an insertion condition, and building a punctured wound with an usable state by cutting by a predetermined breaking part and the movement toward retreat may be possible. A skin contact portion and lancet are designed in the state where it became usable after cutting by a predetermined breaking part inserting into a puncture device again be impossible in practice (it may become possible with the help of auxiliary tools, such as tweezers (tweezers)). Since especially a skin contact portion is very small, only when having combined with the disposable member by the front end of a blood lancet device, it can be attached in practice. So, carrying out the reuse of both used lancet and the used skin contact portion escapes as a matter of fact after cutting of a predetermined breaking part.

[0019] It is protected by the chip protective cap and this chip protective cap is usually connected with a lancet main part via a predetermined breaking part, and the chip of lancet is removed before lancet is used. It is thought that this type of chip protective cap is preferred also in the case of this invention, and the predetermined breaking part between a chip protective cap and a lancet main part is the 2nd predetermined breaking part (the 1st predetermined breaking part in the end point between a skin contact portion and a lancet main part is compensated). A disposable member is designed in this embodiment cut the 1st and 2nd predetermined breaking parts by handling operation of a single time preferably (to coincidence [ Preferably ]). When only a single time moves a hand, I hear that a disposable member is changed into an usable state from an insertion condition, and operation is simplified by such design.

[0020] A predetermined breaking part may be built by the person skilled in the art using the method learned well. Usually, it is the web or strip of a weak material more mechanically than the remaining portion of a disposable member. By it, the component parts (a lancet main part, a skin contact portion, and a chip protective cap when applied) of a disposable member, When mechanical stress is applied by rotating the portion of a disposable member mutually, for example about the axis of the longitudinal direction etc., it dissociates selectively by a predetermined breaking part.

[0021] A disposable member makes a metal lancet needle an exception preferably as a whole, and is a plastic injection molding thing. In this arrangement, a lancet main part, a skin contact portion, and when being applied, a chip protective cap can be manufactured by operation of a single time by a plastic injection molding method, and a needle is located in the axis of the longitudinal direction of a plastic part. In connection with using this method, the predetermined breaking part can take easily the shape of the web of the thin spot which can be cut easily, or injection-

07-A-H07-10210 07/14/2010

molding plastic material.

[0022]The connection between a skin contact portion and a lancet main part does not necessarily need to be direct. In a desirable embodiment, a skin contact portion does not connect with an indirect lancet main part via a chip protective cap in particular, The 1st predetermined breaking part is located in the end point (end of the outlet opening part with which the skin contact portion was equipped) between a skin contact portion and a chip protective cap, and, on the other hand, the 2nd predetermined breaking part is built between a chip protective cap and a lancet main part like usual.

[0023]The disposable member of this invention has a low manufacturing cost. When manufacturing by a plastic injection molding, a manufacture price is hardly different from the price of the lancet usually used with a blood lancet device. In order to avoid carrying out the reuse of the used disposable member, it becomes the further cause that the purchase price is low. In this invention, a chip protective cap is used in order to deal with a disposable member. So, the skin contact portion can become very small as cyclic being intrinsically monotonous preferably. This is preferred as compared with the advanced technology for which the big sleeve for the purpose of handling is needed. In addition to reducing a manufacture price substantially, by designing a skin contact portion as comparatively small component parts, the size as the whole disposable member becomes small as a result, and, so, the capacity of packaging goods becomes small.

[0024]In order to ensure that a device can be operated only by a specific continuous process, the lancet drive mechanism in a desirable mode, It has a means which ensures for the tension load of a repetition of lancet drive mechanism to become possible [ after lancet was removed ], and is arranged in lancet equipment (mounting) between the movement toward the puncture which it precedes, and retreat. Various possibilities for carrying out this function are known. For example, a lever arm is prepared for lancet equipment in the above mentioned US,4442836,B Description, and this lever arm contacts the heights attached between the processes in which load of the tension is carried out, and discharges lancet automatically by it. So, in this arrangement, it is possible to carry out load of the tension to a lancet device only within the case where used lancet is discharged simultaneously. Although the device with a sleeve type skin contact portion was also described above, this has a re-tension load lock so that it can \*\*\*\*, whenever a lancet holder is empty. In addition, a desirable embodiment is especially indicated still in detail to the description of the embodiment which illustrates following this invention.

[0025]the safe protective device (safeguarding) (reuse lock) to the reuse of the skin contact portion which was used and was removed from the device, and/or lancet -- in addition, Since it is ensuring to be unable to use again the lancet which still remains into the device, this type of especially embodiment is advantageous. This can protect thoroughly the danger of infection resulting from the misuse of a blood lancet device as a matter of fact.

[0026]Although this invention is explained more to details using the embodiment which is graphically illustrated to the following figures and is shown in them, this invention is not limited only to this embodiment from the first.

[0027]Drawing 1 shows the blood lancet device 1 of this invention with which the disposable member 3 is inserted in the front end 2. The disposable member 3 contains the lancet 4, the skin contact portion 5, and the chip protective cap 7. The blood lancet device 1 in an usable state is shown in drawing 1, and the lancet 4 is located in the lancet holder 11 in this state, The skin contact portion 5 is installed by the adjustment cap 9 so that the adjustment cap 9 of the housing 10 may close the front opening part 8 except for the outlet opening part 6 for lancet. Since the chip protective cap 7 is removed in the usable state, the dashed line shows drawing 1.

[0028]In the shown embodiment, the puncture of the lancet 4 and the movement toward retreat which are located the lancet holder 11 and in it, It is led by the power conduction cam 15, and this power conduction cam 15 is formed by beginning to delete the crevice of the groove (groove) shape on the surface 14 of circular casing of the lancet holder 11. The power conduction pins 16 of the drive mechanism sleeve 17 provided in the periphery side of the lancet holder 11 in this field engage with said power conduction cam 15. the drive mechanism sleeve 17

-- the inside of the housing 10 -- the blood lancet device 1 -- it is almost extended to the back end (in the direction of a puncture). The coiled spring 18 wound around the spiral in the drive mechanism sleeve 17 which makes the drive mechanism sleeve 17 drive is also located in the back end of the lancet device 1. It lets the coiled spring 18 pass and the ejector 20 with which the front end 20a engages with the lancet holder 11, and the operation button 21 is arranged at the back end works. The drive mechanism sleeve 17 is connected with the intermediate stiffening ring 25 on an operation.

This intermediate stiffening ring 25 can adhere everlastingly with the tension load ring 24, and can \*\*\*\* and stop the adjustment cap 9 on it.

[0029]The housing 10 is grasped in the upper-sleeves part 22, and the right is made to rotate the drive mechanism sleeve 17 according to the tension load ring 24 and a pan with the intermediate stiffening ring 25, in order to carry out load of the tension to the blood lancet device 1 (when it sees the direction of a puncture, and reversely). This motion is told via the drive mechanism sleeve 17 to the coiled spring 18. After the motion which carries out load finishes tension, a restricted (arresting) device (not shown) stops a drive mechanism sleeve, and the coiled spring 18 remains by it with a tension load state. The return spring 27 rotates the intermediate stiffening ring 25 to the first state by motion of a left hand to the drive mechanism sleeve 17 with the tension load ring 24.

[0030]Intrinsically, lancet drive mechanism (the number 12 is attached as a whole) is formed by coiled spring 18, drive mechanism sleeve 17, power conduction pins 16, power conduction cam 15, and ejector 20, is twisted simultaneously, and provides a safeguard. If lancet drive mechanism is released by the deengagement element 28, the power conduction pins 16 arranged in contact with the drive mechanism sleeve 17 and it will rotate at a left hand (when it sees the direction of a puncture, and reversely). The power conduction pins 16 run by this arrangement along with the power conduction cam 15, and the lancet 4 located the lancet holder 11 and in it as a result performs the movement toward a puncture and retreat.

[0031]Furthermore it is related with the lancet drive mechanism used in this illustration embodiment, exact details can be found out on the Germany patent application public presentation No. 4212315 Descriptions.

[0032]The insertion condition before separation of the component parts 4, i.e., lancet, the skin contact portion 5, and the chip protective cap 7 shows the disposable member 3 to drawing 2. The lancet 4 has the lancet main part 31 built with plastic material, and the metaled lancet needle 33 is extended in accordance with the longitudinal direction axis 32 shown with the dashed line in this lancet main part. The both ends of the lancet needle 33 have projected from the lancet main part 31. The front end of the lancet needle 33 which goes in the direction of a puncture is formed as sharp \*\*\*\* 34, and, on the other hand, the back end has the stop surface 35. Although this stop surface 35 is used for positioning of the lancet 4 within the lancet holder 11, especially unlike conventional technology, the lancet needle 33 is equipped with it. It does not prepare for a lancet main part.

The puncture depth which is correctly reproducible can be reached in the process which carries out a puncture succeedingly with the lancet which is different by this even if it is a case where a shallow puncture is used especially. Furthermore it is related with this aspect of affairs, exact details as well as the above can be found out on the Germany patent application public presentation No. 4212315 Descriptions. In the lancet of a description in this Description, a lancet main part has the four isomorphous webs 36 extended along with the whole length, these webs are arranged at intervals of 90 degrees about the longitudinal direction axis 32, and, as a result, a section forms a cross joint (drawing 4). Intermediate (intermediate body) 38 with the sloping contact pressure surface (contact-pressure surface) 39 is located between the webs near the back end of the lancet main part 31 (between the webs).

[0033]The skin contact portion 5 contains intrinsically the disk-like annular solid 41 and the two hook shape engagement elements (hook-likeengaging element) 44 which are fabricated in contact with it and used for wearing on the adjustment cap 9. The front surface of the skin contact portion 5 forms the contact surface 42, and the blood lancet device 1 is pushed against



the skin using this contact surface 42. The distance between the engagement elements 44 which desert the longitudinal direction axis 32 and are curving to hook shape is size from the diameter of the transverse plane 45 of the lancet main part 31. The outlet opening part 6 for the lancet chip 34 is located in the center of the annular solid 41 (shown in drawing 1 in an usable state).

[0034]As described above, a skin contact portion must be small as much as possible by various Reasons. Even if the diameter is large, it is a size about the diameter of the front end 2 of the blood lancet device 1. The size of the skin contact portion of longitudinal direction axis 32 direction containing a wearing element is smallness from 1 cm.

It is smallness from 5 mm preferably.

The size to which a part of skin contact portion which can go in and out from the outside by an insertion condition corresponds should be made quite small so that it may become impossible in practice to insert the skin contact portion 5 independently. In the shown illustration embodiment, only the length D shown in drawing 2 had the skin contact portion [ good ] 5 for the front end 2 of the blood lancet device 1, and it has projected. This size should usually be smallness from 2 mm. In a desirable embodiment, it is smallness from 1 mm.

[0035]As shown in drawing 5, the adjustment cap 9 has the mounting means 54 for exchangeable wearing of the skin contact portion 5. In the shown embodiment, this wearing functions as one mold of a push-in binding. The four shoulders 55 have spread along the circle line of the opening 8 of the adjustment cap 9. The web 56 which works as the rotation restriction stopper 58 behind each shoulder 55 is arranged in the center. The guiding recessed part 57 is located between [ of the shoulder 55 ] each pair.

[0036]As for drawing 2, the chip protective cap 7 is extended later on in the outlet opening part 6 by the shaft 47.

Having the grip region 49 for dealing with the disposable member 3 to the transverse-plane part of the outlet opening part 6 is shown.

The diameter of the outlet opening part 6 should be smallness from 3.5 mm, and is about about 2-2.8 mm preferably.

[0037]The chip protective cap 7 is connected with the circumference of the boundary surface of the outlet opening part 6 with the skin contact portion 5 by the four webs 50 by which division arrangement is carried out uniformly (drawing 3). The web 50 is designed break when the chip protective cap 7 rotates, and forms the 1st predetermined breaking part 52 in this way. The connection between the chip protective cap 7 and the lancet main part 31 is formed of the web 51 which encloses the surroundings with the thin wall between the transverse plane 45 of the lancet main part 31, and the shaft 47 of the chip protective cap 7. This web 51 forms the 2nd predetermined breaking part 53.

[0038]In order to receive the lancet 4, the lancet holder 11 shown in drawing 1 has an acceptance crevice in which the section is a quadrangle intrinsically. A square crevice suits the web 36 (drawing 4) of the lancet main part 31 so that the lancet main part 31 can be introduced in the lancet holder 11 in four different positions which rotated 90 degrees about the longitudinal direction axis 32, respectively. With the engagement element 44, the skin contact portion 5 can also be introduced into the guiding recessed part 57 (drawing 5) of the adjustment cap 9 in these four positions. the tension load tongue-shaped piece (tensioningtongue) which projects the two lugs 61 provided with the inclined end 60 in the acceptance crevice of the lancet holder 11 and by which this lug may be bent with elastic force, respectively -- it is located in contact with 62. It sees reversely [ of the direction of a puncture of the acceptance crevice which crosses \*\*\*\*\* and the direction of a puncture and is run ], and the back end is equipped with the stop element 63.

[0039]In order to insert the disposable member 3, the lancet 4 resists the pressure of the tension load tongue-shaped piece 62, and is introduced into the lancet holder 11, and load of the tension is carried out to the lancet drive mechanism 12 in that case. As a result, the ejector 20 is pushed back. Simultaneously, the lug 61 is slid on the intermediate 38 of the lancet main part 31, and this intermediate approaches each lug. When the movement toward insertion finishes, the two lugs 61 arrive at the contact pressure surface 39 with those inclined ends 60, and, as a result, the disposable member 3 is drawn into the lancet holder 11. If the stop surface 35



touches the stop web 63, the movement toward insertion will be completed. The two hook shape engagement elements 44 are simultaneously introduced into the adjustment cap 9 via the two crevices 57, and, as a result, the hook shape end 44a of the two engagement elements 44 is located in the place same in general as the stop web 56 and a longitudinal direction.

[0040]The disposable member 3 is inserted in the blood lancet device 1 in this position. Usually, if at least one of the two main component parts 4 of a disposable member, i.e., lancet, and the skin contact portions 5 reaches the position of the end of the direction of a motion of a puncture, insertion of a disposable member will be considered to be "completeness" for the purpose of this invention. In the shown embodiment, the lancet 4 located in the lancet holder 11 in an actuated position arrives at a terminal position.

[0041]With an insertion condition, since the predetermined breaking part is unhurt in addition, still, it is not usable in the blood lancet device 1. In order to change it into an usable state, the 2nd predetermined breaking part between the lancet main part 31 and the chip protective cap 7 must be first cut by rotation of the left hand of the chip protective cap 7, or a right hand. By rotating the chip protective cap 7 in the same direction as it further, the engagement element 44 runs against the corresponding stop web 56. The end 44a of the engagement element 44 engages with the shoulder 55 in this position, respectively. For this engagement, when the surface 46 around [ a circular-cone part ] the annular solid 41 contacts to the surface corresponding to the circular-cone part of the adjustment cap 9 further, positioning which can trust the shaft orientations of the skin contact portion 5 and a hand of cut becomes certain. If the movement toward rotation of the chip protective cap 7 is made to continue, the four webs 50 will break and the 1st predetermined breaking part 52 will be cut by it.

[0042]Thus, two predetermined breaking parts are cut by single handling operation, i.e., rotation of the chip protective cap 7, and, as a result, change the blood lancet device 1 into an usable state from an insertion condition. In the state where it dissociated, each element of the disposable member 3 cannot be inserted again (or it can only insert only with remarkable efforts with the help of a tool, but accidental misuse can be avoided by it).

[0043]In the indicated desirable embodiment, it becomes trustworthy [ that the tension load of a repetition of lancet drive mechanism is possible ] [ after removing the lancet located in lancet equipment ] between the movement toward the puncture which it has the means 64 (drawing 1) and precedes by it, and retreat. These means are indicated below.

[0044]The ejector 20 is provided with the discharge protection lug 65 toward which it inclines in the direction of a puncture on the casing surface, and it inclines upward in the shape of a lamp. Furthermore, the front and a center shift to the discharge protection lug 65 on the circumference (offset), and the ejector 20 also has the pin 66 (drawing 1 and 6). the transverse plane of the pin 66 — and a center shifts to the discharge protection lug 65 on this pin and the circumference of the ejector 20, and the \*\*\*\*\* protection lug 67 which inclines upward in the shape of a lamp the direction of a puncture and reversely is formed on the casing surface of the ejector 20. The front end 20a of the ejector 20 is designed by the shape of the letter of a fork in the field of the stop element 63 it be movable to shaft orientations within the lancet holder 11.

[0045]It is shown that drawing 1 has the 1st elastic lock tongue-shaped piece 70 in which the drive mechanism sleeve 17 ranks second according to a direction parallel to shaft orientations first, bends inside slightly near the back end, and projects in the drive mechanism sleeve 17. Furthermore, it has the 2nd elastic lock tongue-shaped piece 71 in which the drive mechanism sleeve 17 follows in the shape direction of an arc in general along a circle line top ahead of the direction of a puncture. The release end of the 2nd elastic lock tongue-shaped piece 71 was provided with the lug 72 which projects inside the drive mechanism sleeve 17, and, as for this lug, the center has shifted to the 1st lock tongue-shaped piece 70 (drawing 6) on the circumference. The 3rd elastic lock tongue-shaped piece 73 oriented with another shaft orientations exists in the transverse plane of the 2nd lock tongue-shaped piece 71 in contact with the drive mechanism sleeve 17. This is located on the internal surface of a drive mechanism sleeve, and forms the existing lamp of the flexibility which inclines upward in the direction of a puncture.

[0046]Now, the drive mechanism sleeve 17 serves as the ejector 20 with the same rank so that

it may be located in the same height, as the pin 66 of the ejector 20 and the 2nd lock tongue-shaped piece 71 show by drawing 1 and drawing 6 during the puncture of the lancet 4, and the movement toward retreat (co-ordinate). this motion of the lancet 4 is brought about by rotation on the left of the drive mechanism sleeve 17 (counter clockwise to a retreat direction) (it is shown in drawing 6 -- as). In this arrangement, the lug 72 of the 2nd lock tongue-shaped piece 71 surpasses the pin 66, moves, and is engaged in that back.

[0047] Since the ejector 20 is protected against rotational movement, rotating to the right hand (counter clockwise to a retreat direction) has the indispensable drive mechanism sleeve 17 to tension load, but it cannot rotate in the direction. So, when the disposable member 3 operates the ejector 20 first, each portion of the must be discharged. The letter front end 20a of a fork of the ejector 20 extrudes the lancet 4 from the lancet holder 11 via displacement with the longitudinal direction axis of the lancet 4 here. The lancet main part 31 pushes the surface of the annular solid 41 between the engagement elements 44 instead at the front 45. As a result, the hook shape end of the engagement element 44 surpasses the shoulder 55, and moves. Then, the skin contact portion 5 and the lancet 4 are discharged.

[0048] Since the ejector 20 is displaced to shaft orientations as mentioned above, now, the pin 66 releases the 2nd lock tongue-shaped piece 71. Therefore, it becomes possible now to carry out load of the tension to the blood lancet device 1 by to rotate the drive mechanism sleeve 17 to the right hand and this rotation. However, during the movement toward discharge of the ejector 20, the \*\*\*\*\* protection lug 67 also surpasses the 3rd lock tongue-shaped piece 73, and moves, and it is engaged in the back. So, \*\*\*\*\* of the ejector 20 indispensable to insertion of the disposable member 3 becomes impossible. Load of the blood lancet device 1 must be first carried out in tension by rotation on the right of the drive mechanism sleeve 17. The \*\*\*\*\* protection lug 67 also rotates to the lock tongue-shaped piece 73 by the rotation, and this \*\*\*\*\* protection lug is released in this way.

[0049] The following stage is that the disposable member 3 is introduced.

The ejector 20 is \*\*\*\*(ed) by as a result forcing the lancet main part 31 to the front end of the ejector 20.

Between this process, since the 1st lock tongue-shaped piece 70 bends, the discharge protection lug 65 moves in the direction which deserts down to the 1st lock tongue-shaped piece 70. Simultaneously, the discharge protection lug 65 will engage with the lock tongue-shaped piece 70, shortly after the disposable member 3 results in an insertion condition within the blood lancet device 1. Before the disposable member 3 changes into an usable state and lancet carries out the movement toward a puncture and retreat by engagement to the discharge protection lug 65 of the lock tongue-shaped piece 70 (not being intentionally), a member is prevented from being disposable discharged 3.

[0050] As a result, on the whole, it sees, and the load of tension, insertion of a disposable member, cutting of a predetermined breaking part, induction of a puncture process, and the operation process of discharge of lancet fully restrain, and are derived.

[0051]

[Effect of the Invention] The skin contact portion and the lancet main part of each other are firmly connected in the disposable member by this invention, By arranging a breaking part to the end point between a skin contact portion and a lancet main part so that a skin contact portion and a lancet main part may dissociate mutually, after a disposable member is inserted, The blood lancet device which can prevent all the reuses of the part which may contact a patient's blood with reliability is provided.

---

[Translation done.]

\* NOTICES \*

JPO and INPIT are not responsible for any damages caused by the use of this translation.

- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.\*\*\* shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

---

## DESCRIPTION OF DRAWINGS

---

### [Brief Description of the Drawings]

[Drawing 1]It is the sectional view which met in the direction of a longitudinal shaft of the blood lancet device of this invention.

[Drawing 2]It is a partial cutting side view of the disposable member of the blood lancet device of this invention.

[Drawing 3]It is a sectional view in alignment with straight-line III-III of the disposable member of the blood lancet device of this invention shown in drawing 2.

[Drawing 4]It is a sectional view in alignment with straight-line IV-IV of the disposable member of the blood lancet device of this invention shown in drawing 2.

[Drawing 5]It is a sectional view in alignment with straight-line V-V of the blood lancet device of this invention shown in drawing 1.

[Drawing 6]It is a sectional view in alignment with straight-line VI-VI of the blood lancet device of this invention shown in drawing 1.

### [Description of Notations]

- 1 Blood lancet device
- 2 Front end
- 3 Disposable member
- 4 Lancet
- 5 Skin contact portion
- 6 Outlet opening part
- 10 Housing
- 11 Lancet holder
- 12 Lancet drive mechanism
- 31 Lancet main part
- 33 Lancet needle
- 42 Contact surface
- 52 The 1st predetermined breaking part

---

[Translation done.]

### \* NOTICES \*

JPO and INPIT are not responsible for any damages caused by the use of this translation.

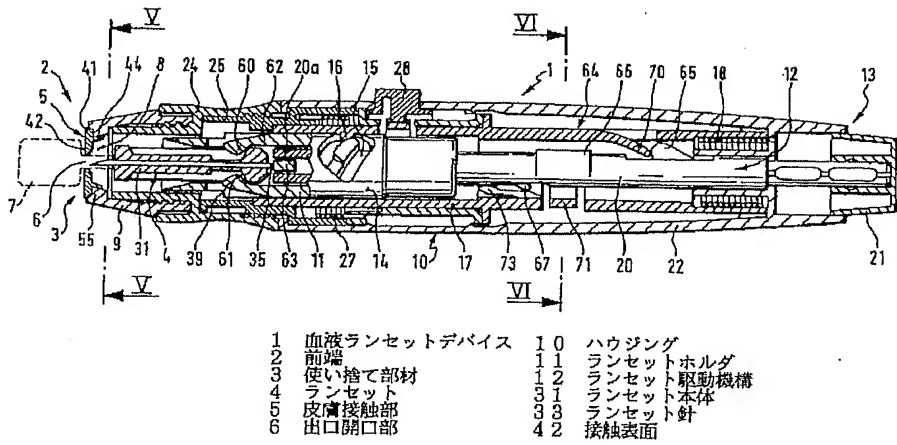
- 1.This document has been translated by computer. So the translation may not reflect the original precisely.
- 2.\*\*\* shows the word which can not be translated.
- 3.In the drawings, any words are not translated.

---

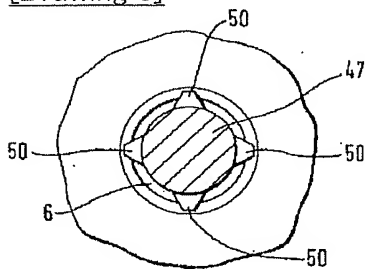
## DRAWINGS

---

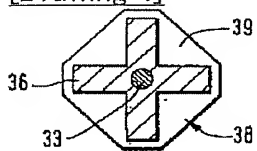
[Drawing 1]



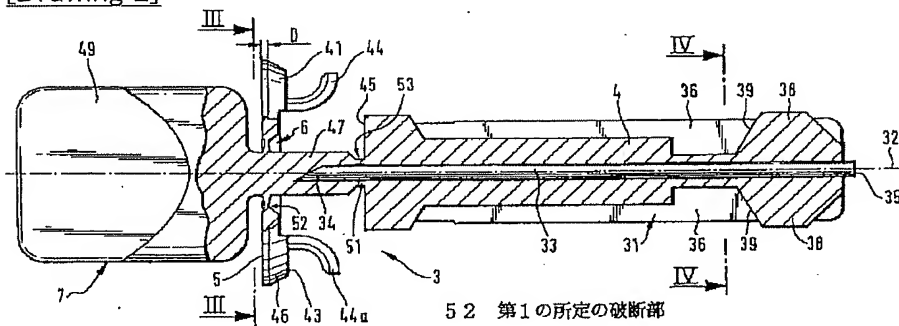
[Drawing 3]



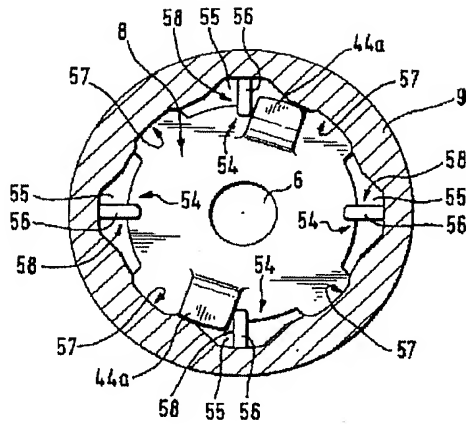
[Drawing 4]



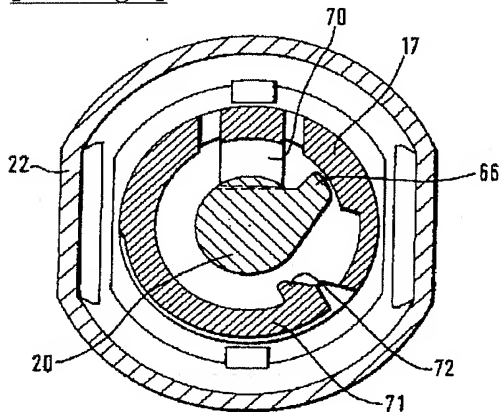
[Drawing 2]



[Drawing 5]



[Drawing 6]



[Translation done.]

## \* NOTICES \*

JPO and INPIT are not responsible for any damages caused by the use of this translation.

1.This document has been translated by computer. So the translation may not reflect the original precisely.

2.\*\*\*\* shows the word which can not be translated.

3.In the drawings, any words are not translated.

## WRITTEN AMENDMENT

[Written Amendment]

[Filing date]Heisei 6(1994) June 21

[Amendment 1]

[Document to be Amended]Description

[Item(s) to be Amended]Claims

[Method of Amendment]Change

[Proposed Amendment]

[Claim(s)]

[Claim 1]A blood lancet device (1) for blood extraction of diagnostic purposes characterized by

comprising the following.

Housing (10).

A lancet holder (11) movable within [ for supporting lancet (4) which consists of a lancet needle (33) fixed in a lancet main part (31) built with plastic material, and this lancet main part (31) ] housing (10).

Lancet drive mechanism (12) for making a puncture of a lancet holder (11) and movement toward retreat which are supporting lancet (4) drive is included in inside, This housing (10) has an exchangeable skin contact portion (5) which has an outlet opening part (6) for lancet (4) in the front end (2) which goes in the direction of a puncture, When this skin contact portion (5) uses a blood lancet device (1), it has a contact surface (42) for pushing against the skin, and this skin contact portion (5) and lancet (4), Component parts of a disposable member (3) which one use is meant and can be inserted by the front end (2) of housing (10) by handling operation of a single time are formed, This disposable member (3) is designed lancet (4) accept it with a skin contact portion (5), inserted, and get, Within this disposable member (3), lancet main part (31) of each other is connected with a skin contact portion (5), The 1st predetermined breaking part (52) that a skin contact portion (5) and a lancet main part (31) may separate mutually after a disposable member (3) is inserted in an end point between a skin contact portion (5) and a lancet main part (31).

---

[Translation done.]